DEPARTMENTS OF THE ARMY AND THE AIR FORCE
NATIONAL GUARD BUREAU
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ARLINGTON, VA 22204-1382

NGB-ARP

26 JUL 1996

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: (All States Log Letter I96 -0164) Army Compliance With Clinical Laboratory Improvement Program (CLIP) Training

1. Referenced the enclosed memorandum from the Armed Forces Institute of Pathology dated 23 May 1996 with enclosures. This guidance is provided for your review and compliance.

2. Note that the fifteen week initial entry trained Basic Medical Laboratory (BML) course graduates of all components will not be qualified to perform supervisory laboratory duties after 1 September 1997.

3. Although force structure changes limit the impact of these requirements on the ARNG, compliance where applicable is vital since the provisions are public law.

4. The POC is MSG Lansing at DSN: 327-7145 or CML: 703-607-7145.

FOR THE CHIEF, NATIONAL GUARD BUREAU:

Encls
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RONALD J. TIPA
COL, GS
Director of Personnel

DISTRIBUTION:
State Surgeon
MILPO

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DEPARTMENT OF DEFENSE
ARMED FORCES INSTITUTE OF PATHOLOGY
WASHINGTON, DC 20306-6000

REPLY TO
ATTENTION OF

AFIP-ZD

23 May 96

MEMORANDUM FOR

HQDA OTSG, DASG-PSZ, Health Services Directorate, ATTN:COL O'Brien, 5109 Leesburg Pike, Falls Church, VA 22041

USAMEDCOM, Director, Health Care Operations, ATTN:COL Day, 2050 Worth Road, Ft. Sam Houston, TX 78234

OCAR, DAAR-MA, Medical Affairs, Pentagon 1E440. Washington, DC 20310-2400

USARC, AFRC-MD, Office of the Surgeon, 3800 Camp Creek Parkway, SW, Atlanta, GA 30331

✓ National Guard Bureau, ARGN Readiness Center, ATTN:NGB-ARP-HN, Arlington, VA 22204

SUBJECT: Action for Army Compliance with the Clinical Laboratory Improvement Program (CLIP) Personnel Training Requirements for the 91K MOS

1. In 1994, the OTSG-appointed process action team recommended to the Deputy Surgeon General that the new training plan for enlisted medical laboratory specialists (MOS 91K) submitted by the AMEDDC&S be approved to bring the Army into compliance with CLIP personnel training requirements. At that time, a recommendation was made for personnel at the Office of Clinical Laboratory Affairs (OCLA), AFIP, to submit a request for an extension of the 1 Sep 97 deadline for enlisted personnel performing high complexity testing to have earned an Associate Degree. The request to be submitted to ASD(HA) was to be for negotiation with the Health Care Financing Administration (HCFA) and the Department of Health and Human Services (DHHS). The need for extension was to be based on a lack of training seats to bring all Components of the Army into compliance with the requirement by the deadline date. Background information concerning the CLIP personnel requirements is enclosed as an information paper.

2. A request for extension of time for enlisted personnel to meet the CLIP personnel requirements is no longer needed and will not be pursued by the OCLA. Previous discussion on the potential for the Army to request an extension to meet 91K MOS personnel requirements of the Clinical Laboratory Improvement Program (CLIP) are no longer germane. Changes to personnel requirements published in the 24 Apr 95 Federal Register allow the Army to meet laboratory testing and supervisory personnel requirements. Reclassification action is being pursued to insure properly trained supervisors are available in all Components (See enclosure 1).

3. Prior to the announced change, an associate degree was required for personnel to perform and supervise laboratory testing. The AMEDDC&S could not accommodate the required student load to enable all Components of the Army to comply with this requirement. The new requirement is an equivalency to the associate degree that can be met by graduates of a military training program of at least 50 weeks duration. These graduates, after obtaining sufficient college credit, meet mandatory training requirements to perform, and with 2 years experience, to supervise high complexity testing on the effective date of CLIP personnel requirements (1 Sep 97).

4. A major personnel problem for the AMEDD now is the large number of 15-week initial entry trained Basic Medical Laboratory (BML) course graduates in all Components (last graduating class - Dec 94) who are not qualified and cannot perform supervisory laboratory duties after 1 Sep 97. This supervision composes the technical portion of their NCO duties. If they cannot supervise their technical specialty, they cannot be NCOs in that specialty. All soldiers graduating BML after 1 Sep 82 are affected. Those graduating before 1 Sep 82 are grand fathered. Additionally, approximately 350 of these soldiers in the Active Component, have not yet been able to attend training at the AMEDDC&S, and now, because of promotion policies and retention control points, some of them will be ineligible to either attend a 52-week training course or to re-enlist.

5. **Reserve component missions where whole units with laboratory assets deploy will be severely compromised.** There was no previous requirements for Reserve Component personnel to return for additional training after the 15 week IET course. Therefore, large numbers of these soldiers populate the USAR and NG 91K MOS billets. Adequate supervision of test performance without augmentation by Active Duty soldiers will not be available. The Surgeon General can waive some components of CLIP in time of war, or other mobilization actions, but lowering the personnel standards could jeopardize the quality of laboratory care provided to deployed soldiers. Blood banking and microbiology are major components of deployed unit responsibilities.

6. Effect on other Active and Reserve Component missions is less drastic, but is still a significant problem. Backfill of 91K to Europe for Operation Joint Endeavor has caused significant problems is the performance of laboratory work at the Wuerzburg Community Hospital. Data is currently being gathered by the USAR concerning the training, experience, and job knowledge of the 91K Reserve soldiers being sent to Europe.

7. The Reserve Components have been unable to fill many of the school training seats they were allocated. OCAR personnel made a conscious decision not to send BML-trained Reserve soldiers back to the AMEDDC&S or to local colleges for the 52-week training requirement. They elected to address the problem through attrition and/or reclassification with future 91K positions to be filled by new IET soldiers. This decision was purely economic. The Reserves were to fill Contingency Force Package I positions with priority.

8. Because of the USAR drawdown, and lack of action to re-classify Reserve 91K soldiers who have only BML training, the number of new recruits for the Reserves in MOS 91K has slowed to a trickle. In an attempt to alleviate this problem, the Army Personnel Proponency Directorate is currently staffing the following AR 611-201 reclassification actions:

a. All Reserve Component SSG and SFC who graduated BML after 1 Sep 82 must meet the new requirements by 1 Sep 97 or be reclassified.

b. All Reserve Component soldiers in grades PVT through SGT with only BML training must meet the new requirements for promotion to SSG.

c. All Active Duty and Reserve backfill medical laboratory specialists must meet the new requirements by 1 Oct 99 or be reclassified. BML graduates may continue to perform high complexity testing with appropriate supervision until 1 Oct 99.

d. The remaining Reserve Component medical laboratory specialists must meet the new requirements by 1 Oct 02 or be reclassified. BML graduates may continue to perform high complexity testing with appropriate supervision until 1 Oct 02.

9. Publication of revised CLIP personnel training requirements for medical laboratory specialists and medical laboratory supervisors allows the Army to comply with CLIP without requesting an extension of time from the DHHS. A defined problem exists with USAR unit deployments and USAR backfills to AD hospitals.

10. If there are questions concerning this memorandum, I can be reached at DSN 295-7235, or Commercial (301) 295-7235.

Charles V. Watson

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CHARLES V. WATSON
LTC, MS
Center for Medical Laboratory Affairs

AFIP-ZD
16 Apr 96

INFORMATION PAPER

ARMY COMPLIANCE WITH CLIP PERSONNEL TRAINING REQUIREMENTS

1. PURPOSE: To provide background on the decision not to request an extension for Army compliance with CLIP personnel training requirements.

2. BACKGROUND:

a. Public Law 100-578 (Clinical Laboratory Improvement Amendments of 1988 (CLIA)) mandated national implementation of a massive medical laboratory quality improvement program. Federal facilities are subject to this law. Implementation within the military is governed by a memorandum of understanding between the Secretary of Health and Human Services and the Assistant Secretary of Defense (Health Affairs). This MOU has been formalized into DODI 6440.2 (20 Apr 94) which directs implementation of the military CLIA equivalent program called the Clinical Laboratory Improvement Program (CLIP).

b. Personnel training standards for working in medical laboratories were radically altered by CLIA. Testing was initially divided into 3 categories based on complexity. They were minimal complexity, moderate complexity and high complexity. Even after some revisions, this strategy of test complexity still survives. Personnel requirements increase as test complexity increases. Initially, an associate degree was required by 1 Sep 97 for anyone performing or supervising high complexity testing. This requirement was in place in 1993 when the Medical Functional Review and AMEDD Functional Area Assessment (Dec 93) was briefed to Army personnel chiefs and was the main reason for discussion on a potential Army extension for compliance with the law.

c. AMEDDC&S submitted required curriculum changes to OTSG to bring its training program into compliance with CLIP. OTSG convened a process action team (91K Medical Laboratory Specialist PAT) to evaluate these changes. Members of the team consisted of active, reserve and national guard components. Its report was accepted and signed on 15 Apr 94 by BG Nancy R. Adams, Director of Personnel and on 19 Apr 94 by MG Thomas Tempel, Deputy Surgeon General.

d. Recommendation 7 (page 5) stated: "Seek extension for 100% compliance with personnel requirements for testing personnel due to inability to handle student load - separate action (POC AFIP-ZD)." The reasoning for this recommendation was expanded on pages 8 and 9 of the report (enclosure 1). No action was taken because DHHS stated that new personnel requirements were under consideration. Action was postponed pending publication of the new requirements.

3. Changes to CLIP personnel training requirements:

New personnel requirements were announced on 24 Apr 95. An equivalency to the associate degree requirement was published. Basically any graduate from a military medical laboratory training program of at least 50 weeks duration is considered fully qualified to perform, and with additional experience, supervise high complexity testing if they graduated on or before 24 Apr 95. Graduates from the same course after 24 Apr 95 require 60 semester college credit hours to be qualified as either testing personnel, or supervisor (AMEDDC&S is working on obtaining the required college credit).

Based on this change, Army graduates of the required length military training are qualified to perform and supervise high complexity procedures (for example, blood banking and microbiology) after the effective date of CLIP personnel requirements (1 Sep 97). Supervision of these procedures is inherent to successful performance of NCO duties.

4. Effect on the Army:

a. The Army's problem is the large number of 15 wk initial entry trained soldiers. These soldiers are allowed to continue to perform high complexity testing with appropriate supervisory review of their work after the 1 Sep 97 training deadline. However, they cannot perform technical supervisor (NCO) duties. If they graduated on or before 19 Jan 93 their work needs to be reviewed by a qualified supervisor within 24 hr. If they graduated between 20 Jan 93 and Dec 94 they can only perform high complexity work under direct supervision of a qualified supervisor. Soldiers with only BML training who graduated after 1 Sep 82 do not qualify as supervisors after 1 Sep 97, therefore cannot perform the technical component of their NCO duties.

b. Active duty BML trained soldiers returned for the 52 wk Advanced Medical Laboratory (AML) training course prior to promotion to SFC. There was no requirement for this training for the Reserve components. AML has been replaced by a specifically designed 52 wk MLT course for BML graduates. This course started in Oct 93. Most attendees are from the Active component. Reserve component training slots have not been filled in this course. The Army Reserve made a conscious decision to not send soldiers back to the MLT course designed for BML graduates. The Army Reserves have a high percentage of BML graduates. The National Guard is sending some soldiers to MLT.

c. Projected status of training in each component at the 1 Sep 97 deadline:

(1) Active Duty - approximately 200-250 soldiers will remain to be trained.

(2) USAR - most NCOs will not meet supervisory requirements.

(3) National Guard - Some NCOs will not meet supervisory requirements.

5. Impact on readiness:

a. **Active Duty. Minimal** effect because of small number of untrained soldiers and sufficient number of qualified NCOs. Soldiers will be handled on an individual basis to provide appropriate supervision. Failure to take the MLT course will result in reclassification.

b. **Reserve Components. Mixed, but more serious.**

(1) Unit deployment. **Reserve component missions where whole units with laboratory assets deploy will be severely compromised.** There was no previous requirement for reserve component personnel to return for additional training after the 15 week IET course. Therefore, a large number of these soldiers populate the USAR and NG 91K MOS billets. No

adequate supervision of test performance without augmentation by Active Duty soldiers will be available. The Surgeon General can waive some components of CLIP in time of war, or other mobilization actions. Lowering the personnel standards could jeopardize the quality of laboratory care provided to deployed soldiers. I must point out that blood banking and microbiology are major components of deployed unit responsibility. Effect on other Active and Reserve Component missions is less drastic.

(2) Backfill mission. Backfill and caretaker missions may be affected depending on the number of remaining civilian supervisors at these locations. If no, or few civilians remain, mission completion cannot be guaranteed within present requirements.

(3) Physicals and Guard Care. Minimal impact because only moderate complexity procedures are performed.

LTC WATSON/AFIP-ZD/DSN 295-7235

Discussion of Recommendations (continued)

ACASP in the past 5 years), STAR, Laboratory Demonstration Project, or some other option, is essential . Normal programmed changes in training leading to gradual upgrades in knowledge base are not viable under CLIA. A national deadline has been established that forces a search for feasible alternatives to all military training. The next recommendation addresses our inability to realistically meet the Sep 97 training deadline.

7. Recommendation: Seek extension for 100% compliance with personnel requirements for testing personnel due to inability to handle student load - separate action.

Discussion: This is a separate action discussed as an option at both the FR and FAA. Thorough analysis of the Army's training capability, and evaluation of alternate recruitment methods demonstrates the enormity of this problem. CLIA national standard calls for personnel performing high complexity testing to have an associate degree by Sep 97 or they cannot routinely perform those tests. Most of Microbiology and Blood Banking falls into this categorization. One recent scenario (Tab D) results in training for approximately 100% AD soldiers and the number of soldiers in RC CFP 1 and 2 and Caretaker packages by Oct 99. This covers approximately 45% of reserve soldiers being MOSQ. Reserve components presently maintain a 70% MOSQ (briefed at FR and FAA). They will not meet this target until Oct 01. Even a successful outservice training program can not realistically result in compliance by Sep 97. Depending upon the mix of soldiers stationed at MTFs, laboratory services may have to be curtailed. Additional problems will occur with RC MTF caretaker missions when those facilities are expected to provide peace time quality health care while another part of the force is deployed. TSG has the authority under CLIP to relax personnel criteria upon deployment. Until the active component is trained to 100% MOSQ, and reserve components to 70% MOSQ, the Army is vulnerable. DoD agreed to implement CLIA within the military except where prohibited by military exigencies. The target for personnel standards is Sep 97. Both Navy and Air Force have trained to the 50 week standard for some time. The Army is alone in this problem. OASD(HA) is willing to accept a request for extension to the deadline for applying personnel standards, as long as the request does not include services provided by fixed facilities. An extension will allow deployment of BML qualified soldiers until there are sufficient MLT qualified soldiers in the inventory. Continued use of BML graduates in fixed facilities with sufficient supervision will be a policy decision of OASD(HA), and not an arbitrary decision by the TSG. As long as the Army is showing progress towards complete compliance, there

Enclosure 1 (Info Paper)

Discussion of Recommendations (continued)

is a good chance for success with the request. Failure to ask for or receive the extension will require a complete reevaluation of the Army's plan for implementation of CLIP. Requesting the extension has nothing to do with approving the ITP except that the size of the effort is vastly increased without it. Discussion is mentioned here to provide a complete evaluation of outside influences on the ITP.

8. Recommendation: Stop outcalls from 91K MOS to allow staffing until first graduates of new course are available for assignment.

Discussion: TAPC has made this a reality. 91K staffing is expected to be 115 - 117% at the end of FY 94.

9. Recommendation: Use SMDR process to determine specific TTHS requirements.

Discussion: Initiation of the new ITP results in a dramatic increase in the TTHS account. Most recent estimates are increases totaling 541 man years (352 AD, 17 NG, 172 USAR) per year during FY 95-99 (There is a gradual decrease in AD over this time that is offset by a corresponding increase in required TTHS for USAR). Starting in FY 02 the permanent increase goes to 586 man years per year when compared to FY 93 levels (attachment 3). According to DAPE-MBI and DACS-DPD(PA&E), this increase can be handled within manpower ceilings in FY 95. Increases in FY 96 and beyond need to be planned for in the normal programming process. The specific increase for FY 95 will be verified in the SMDR process.

10. Recommendation: AMEDDC&S to seek accreditation from a nationally accrediting body for the course.

Discussion: CLIA and CLIP require associate degrees for personnel performing high complexity work after 1 Sep 97. Even if an equivalency training requirement is published in lieu of the associate degree requirement it will be based on technical training. This training will be required to be obtained in an accredited institution. AMEDDC&S BML is not accredited because it does not meet programmatic requirements of national accrediting bodies. The new MLT provides sufficient training to meet national accrediting requirements. Both Navy and Air Force programs are accredited.

Enclosure 1 (Info Paper)